

August 29, 2002

Sandra Titus
Advisors and Consultants Staff
FDA/CDER
5630 Fishers Lane
Rockville, MD 20857

RE: NDAC Meeting-Acetaminophen-September 19, 2002

This letter is written on behalf of the National Association of Pediatric Nurse Practitioners and its 6,700 members in reference to the NDAC hearings regarding over the counter medications (OTC); specifically acetaminophen. Pediatric nurse practitioners in our organization serve as primary care providers and specialty care providers to thousands of children throughout the United States. In this capacity, over the counter medications are recommended for patient use on a frequent basis in clinical practice.

Pediatric nurse practitioners (PNPs) have long been influential patient educators and in no arena is this more evident than in directing the patient use of OTC medications. Acetaminophen is one of the most frequently used products in the care of children in our practices. It serves a critical function for fever management, but is also important in managing pain as well. For infants under three months of age, it is only approved fever management product. When used as directed, it is extremely safe and effective. PNPs have spent a significant portion of time in office encounters educating patients and families in the appropriate use of the different concentrations of acetaminophen products. This is especially important in the field of pediatric practice, as the weight of the patient is critical to ensuring the appropriate dosage. For this reason, PNPs have been actively engaged in the process of communicating the message of safe use of these products and continue to do so for our patients.

It is our hope that these meetings will provide creative solutions on the means to continue to address issues of safety of acetaminophen usage, without negatively impacting availability of this OTC medication to the public. We feel that any decisions for change should be based on scientific evidence, particularly regarding formulation and dosage. It is most important to retain the wide availability of this essential OTC medication, with the understanding that proper use of the product as labeled is critical. Pediatric nurse practitioners will continue to highlight the principles of the safe and effective use of acetaminophen products in their clinical practices.

Sincerely,

Eileen K. Sandifer

Eileen K. Sandifer, CPNP, MSN
National Association of Pediatric Nurse Practitioners

Enclosures